

Appl. No. : 09/646,950  
Filed : December 8, 2000

### REMARKS

Claims 1, 3, 12-15, 18, 19, 38, 42, 55, 56 and 59 have been amended, Claims 8-11, 17, and 55 have been cancelled without prejudice, and new Claims 62-68 has been added. Claims 1-4, 12-16, 18-21, 38-42, 52-54, and 56-68 remain pending in the present application. Support for the amendments is found in the Specification and claims as filed. Accordingly, the amendments do not constitute the addition of new matter. Reconsideration of the application in view of the foregoing amendments and following comments is respectfully requested.

#### Claim Objections

The Examiner objected to Claim 8 under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. The Examiner objected to Claim 11 under 37 C.F.R. § 1.75(c) as being of improper form because a multiple dependent claim cannot depend from another multiple dependent claim. Claims 8 and 11 have been cancelled without prejudice. Accordingly, the claim objections are now moot.

#### Claim Rejections under 35 U.S.C. § 112, first paragraph

The Examiner rejected Claims 1-4, 8, 9, 11, 13-17, 19, 38-42, and 55-60 under 35 U.S.C. § 112, first paragraph, for not providing enablement for the full scope of inhibiting an immune response for the full scope of asparaginyl endopeptidase inhibitors that are "asparagine-containing." The Examiner also rejected Claims 15-17, 19, 38-42, 55, 56, and 60 under 35 U.S.C. § 112, first paragraph, for not providing enablement for the full scope of asparaginyl endopeptidase inhibitors or their administration of in general.

Claim 1 has been amended to incorporate the allowable subject matter of Claim 10. Accordingly, Claim 1 and dependent claims therefrom, namely Claims 2-4, 13-14, 57-59, and 68 are allowable.

Claims 15, 38, and 56 have been amended to recite, *inter alia*,

the inhibitor of asparaginyl endopeptidase is a competitive inhibitor comprising a peptide selected from the group consisting of Ala-Glu-Asn-Lys-NH (AENK) and Lys-Asn-Asn-Glu-NH (KNNE); or

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the inhibitor of asparaginyl endopeptidase is a non-competitive inhibitor of asparaginyl endopeptidase which comprises an asparagine residue to which is attached a group capable of reacting with active site cysteine of asparaginyl endopeptidase.

The limitation of the competitive inhibitor is based on allowable subject matter of Claim 10.

The limitation of the non-competitive or irreversible inhibitor is supported by the Specification from page 7, line 27 to page 13, line 18. This claim scope is also believed to be fully enabled and described by the written description of Specification. Specifically, page 8 of the Specification discloses that "the peptide sequence has the C-terminal residue as an asparagine residue to which is attached the group which reacts with the active site cysteine." The generic formulas, as recited in some of the claims, for instance B1-(X)<sub>n</sub>-Asn-Q or (Xb-Xc)Asn(Xd-Xe), are some examples of the recited inhibitors. Additional irreversible inhibitors meeting the limitation of the claims are also effective. For instance, inhibitors meeting the limitation of the claims are disclosed in a later publication of the inventor in the Loak et al. publication (attached hereto). This publication shows that a number of additional compounds meeting the limitation of the claims are effective in inhibiting the immune response. Therefore, the disclosure of the Specification at page 8 gives enabling support that inhibitors having a "an asparagine residue to which is attached a group capable of reacting with active site cysteine of asparaginyl endopeptidase" are effective. Accordingly, Claims 15, 38, and 56 and dependent claims therefrom are believed to be patentable.

Claim 42 has been amended to be dependent on allowed Claim 52. Claim 55 has been cancelled without prejudice.

Accordingly, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection under 35 U.S.C. § 112, first paragraph.

Claim Rejection under 35 U.S.C. § 112, second paragraph

The Examiner rejected Claims 11 and 12 under 35 U.S.C. § 112, second paragraph, as being indefinite. In particular, the Examiner stated that there is no antecedent basis for the limitation "wherein the inhibitor is a non-competitive or irreversible inhibitor" in Claim 11. Claim 11 has been cancelled without prejudice. Claim 12 has been amended to be dependent on new Claim 62, which provides basis for all limitations of Claim 12. New Claim 62 reciting the

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non-competitive or irreversible inhibitor is supported by the Specification from page 7, line 27 to page 13, line 18. This claim scope is also believed to be patentable and free of the prior art.

Accordingly, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection under 35 U.S.C. § 112, second paragraph.

#### Allowed Claims

The Examiner has allowed Claims 52-54 and 67, and has indicated that Claims 10, 12, 18 and 20 would be allowable if rewritten in independent form. The subject matter of Claim 10 has been incorporated into Claim 1. Claim 42 has been amended be dependent on Claim 52. Accordingly, Claim 1 and dependent claims therefrom, namely Claims 2-4, 9, 13-14, 42, and 57-59 are allowable.

#### CONCLUSION

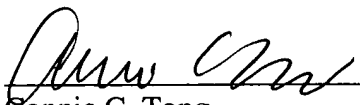
In view of the foregoing amendments and comments, it is respectfully submitted that the present application is fully in condition for allowance, and such action is earnestly solicited.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully invited to call the undersigned in order to resolve such issue promptly.

Respectfully submitted,

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Dated: December 5, 2005

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